REMARKS

Applicants have amended claims 1-5, cancelled claims 6-7 and added claims 8-16 to more accurately define the invention.

Rejection Under 35 U.S.C. § 112

The Examiner has rejected claims 4 and 5 under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and claim the subject matter the Applicant regards as the invention. Applicant respectfully points out that the amendments to claims 4 and 5 render the rejections moot and request their withdrawal.

Rejections Under 35 U.S.C. § 103(a)

The Examiner has rejected claims 1, 2, 6 and 7 under 35 U.S.C. § 103(a) as being unpatentable over Dorn et al. (U.S. Patent No. 4,980,057) (*hereinafter* "Dorn") in view of Browner et al. (U.S. Patent No. 4,629,478) (*hereinafter* "Browner"). The Applicant has cancelled claims 6 and 7 rendering their rejection moot. The Examiner states that both references involve systems which couple chromatographic separators, production of aerosols for analysis and downstream mass spectrometer detectors. The Examiner argues that Dorn discloses a chromatographic separator a vacuum unit for evaporating and concentrating and a device for preventing flow rates through the separator from being affected by the vacuum using a capillary restrictor. The Examiner further states that Browner discloses a pump and metering means and therefore it would have been obvious to one of ordinary skill to utilize the pump and metering means of Browner in the Dorn system. The Applicant respectfully traverses this rejection.

"In order to rely on a reference or references as a basis for rejection of Applicant's invention, the references must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the inventor was concerned." In re Oetiker, 977 F.2d 1443, 1446, 24 USPQ2d 1443, 1445 (Fed. Cir. 1992).

The Applicant submits that both the Dorn and Browner references disclose apparatus used to connect two analytical instruments, a HPLC and a mass spectrometer, which are not analogous to the present invention, and therefore cannot form the basis of an obviousness rejection. The present invention relates to a sample preparation apparatus that interfaces a chromatographic separation device with an evaporative vacuum unit that concentrates the sample back to its original volume, and thereby cleans samples for use in other analytical instruments. The present invention combines the two analytical sample preparation processes into one apparatus which is capable of doing them simultaneously. There is nothing in the prior art which shows these two sample preparation processes combined. The two processes are coupled by means of a back pressure regulator which separates the chromatographic separation process from the evaporative process by preventing the constant flow rate from being affected by the vacuum present in the evaporator.

Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either explicitly or implicitly in the references themselves or in the knowledge generally available to one of ordinary skill in the art. "The test for an implicit showing is what the combined teachings, knowledge of one of ordinary skill in the art, and the nature of the problem to be solved as a whole would have suggested to those of ordinary skill in the art." In re Kotzab, 217 F.3d 1365, 1370, 55 USPQ2d 1313, 1317 (Fed. Cir. 2000).

In both Dorn and Browner, the desolvation chambers have helium or another inert gas pumped in at high temperature and flow rates. All of the solvent is evaporated and removed from the sample so that ionization of the compounds in the sample can occur. This is the opposite of what happens in the evaporator of the present invention. During operation, the solvent with the sample elutes into the evaporator chamber and is evaporated at a rate approximately equal to the incoming flow rate until the entire sample has eluted from the column. There is no inert gas used in the process. The evaporation continues until only a predetermined volume remains, typically 5 mL but it can be varied. It is important to understand that the solvent is not eliminated from the sample in the present invention. Moreover, in both Dorn and Browner, the sample containing the solvent is supplied in a finely dispersed aerosol

using a low-pulse liquid pump. There is no aerosolization process in the present invention. Therefore one of ordinary skill in the art would not have been motivated to consider either the Dorn or Browner references when deciding on how to eliminated impurities in a dissolved sample and have the sample reconstituted into the same volume simultaneously and in an automated fashion.

To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. In re Royka, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). The Applicant submits that in view of the amended claims none of the cited references include the limitation that the samples are simultaneously precleaned and evaporated to a predeterminable volume for later analysis.

The Examiner has rejected claims 3-5 under 35 U.S.C. § 103(a) as being unpatentable over Dorn et al. in view of Browner et al. as to claims 1 and 2 above, and further in view of Walters et al. (U.S. Patent No. 6,086,767) (*hereinafter* "Walters"). The Examiner states that claims 3-5 differ in requiring the means for preventing to be a valve or specifically a back pressure regulator type valve. The Examiner further states that Walters teaches a plurality of such back pressure regulator restrictor valves and it would have been obvious to one of ordinary skill in the art to have further modified the Dorn system by substituting a back pressure regulator type valve. The Applicant respectfully traverses the rejection.

With regard to the rejection of claims 3-5, Applicant maintains the arguments made with respect to the Dorn and Browner references made in traversing the rejection of claims 1 and 2 above. Furthermore, Applicant asserts that the Examiner has failed to demonstrate that there is some teaching, suggestion, or motivation found either explicitly or implicitly in the references themselves or in the knowledge generally available to one of ordinary skill in the art, that one of ordinary skill in the art would be motivated to look to Walters to apply a back pressure regulator to the system described by Dorn.

The Examiner has put forth no motivational basis for making the assertion that a valve used for supercritical heating and pressurizing a solvent (Walters) would have any relevance to

one of ordinary skill using LC/MS (Dorn or Browner). The Examiner has stated that one of skill in the art would do this to "optimize timing and volume of sample movement and prevent necessity of wasting and discarding of sample volumes" (page 3 of Office Action). The initial burden is on the Examiner to provide some suggestion of the desirability of doing what the inventor has done. "To support the conclusion that the claimed invention is directed to obvious subject matter, either the references must expressly or impliedly suggest the claimed invention or the examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references." Ex parte Clapp, 227 USPQ 972, 973 (Bd. Pat. App. & Inter. 1985). When the motivation to combine the teachings of the references is not immediately apparent, it is the duty of the Examiner to explain why the combination of the teachings is proper. Ex parte Skinner, 2 USPQ2d 1788 (Bd. Pat. App. & Inter. 1986). The Applicant submits that the Examiner has not identified any such motivational basis, or if such basis exists, it is found in Applicant's disclosure. As such, the Applicant respectfully states that the rejection of claims 3-5 under 35 U.S.C. § 103(a) is improper and requests its withdrawal.

All of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. The Applicant therefore respectfully requests that the Examiner reconsider all currently outstanding rejections, and that they be withdrawn. It is believed that a full and complete response has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Respectfully submitted,

JACOBSON HOLMAN PLLC

400 Seventh Street, N.W.
Washington, D.C. 20004-2201
(202) 638-6666
Date: March 26, 2004
Atty. Docket: 347/P67239US0
HBJ/JGC/clc

Joseph G. Contrera
Registration No. 44,628